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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,924	02/12/2002	Rebecca Redman	INBI-009/01US	1990

23419 7590 09/08/2004

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EXAMINER

SHANNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,924	REDMAN ET AL.	
	Examiner	Art Unit	
	Khatol S Shahnan-Shah	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 10-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 10-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicants' amendment of May 07, 2004 is acknowledged. Claims 1, 10 and 17 have been amended. Claims 9 and 24 have been canceled.

2. Claims 1-8 and 10-23 are pending and under consideration.

3. Applicants' declaration under 37 CFR 1.132 of April 29, 2004 is acknowledged.

The declaration of Rebecca Redman, M.D. under 37 CFR 1.132 filed April 29, 2004 is sufficient to overcome the rejection of claims 1-8 and 10-23 based upon 35 USC 102/103 as being anticipated by or, in the alternate as obvious over Kollef et al.

Prior Citations of Title 35 Sections

4. The text of those sections of Title 35 U.S. Code not included in this action can be found in a prior office action.

Prior Citations of References

5. The references cited or used as prior art in support of one or more rejections in the instant office action have been previously cited and made of record. No form PTO-892 or 1449 has been submitted with this office action.

Rejection(s) Moot

6. Rejections of claims 9 and 24 under 35 U.S.C. 112, second paragraph, made in paragraph 8 of the office action mailed December 12, 2003 is moot in view of cancellation of said claims.

7. Rejections of claims 9 and 24 under 35 U.S.C. 102/103, made in paragraph 12 of the office action mailed December 12, 2003 is moot in view of cancellation of said claims.

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Rejection(s) Withdrawn

8. Rejections of claims 1-8 and 10-23 under 35 U.S.C. 112, second paragraph, made in paragraph 8 of the office action mailed December 12, 2003 is withdrawn in view of applicants' amendments and arguments.
9. Rejections of claims 1-8 and 10-23 under 35 U.S.C. 102/103, made in paragraph 12 of the office action mailed December 12, 2003 is withdrawn in view of applicants' declaration.
10. Rejections of claims 1, 2, 4, 7, 17, 19 and 22 under 35 U.S.C. 102(b) as being anticipated by Steinberg et al. (WO 00/04915) made in paragraph 10 of the office action mailed December 12, 2003 is withdrawn in view of applicants' amendments.

Rejection(s) Maintained

11. Rejections of claims 4-8 and 19-22 under 35 U.S.C. 112, first paragraph, made in paragraph 6 of the office action mailed December 12, 2003 is maintained.

The rejection was as stated below:

Claims 4-8 and 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a 0.3 wt% composition of IB-367, does not reasonably provide enablement for 0.03 wt% composition of IB-367. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/or use the invention commensurate in scope with these claims.

Claims 4 and 19 recites a composition of about 0.03 wt% to about 0.3 wt% of IB-367. The specification is only enabled for a 0.3 wt% composition of IB-367 (see page 8 composition and page 11 experimental protocol). The instant specification invites the skilled artisan to

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experiment. The factors, which must be considered in determining undue experimentation, are set forth in In re Wands USPQ2d 14000. The factors include

- 1) quantity of experimentation necessary,
- 2) the amount of guidance presented,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the predictability of the art and the
- 7) breath of the claims.

With regard to factors one and two cited above the quantity of experimentation needed to determine amounts of the active ingredients (i.e 0.03 wt%), the timetable necessary to achieve efficacious administration, dosage frequency.

With regard to factors three and seven, it is noted that the working examples are limited to a 0.3 wt% composition of IB-367. Such is not seen as sufficient to support the breath of the claims, wherein the scope of the claims encompasses a wider range of efficacy of the instantly claimed compounds and/or compositions. It is noted that Law requires that the disclosure of an application shall inform those skilled in the art how to use applicant's alleged discovery, not how to find out how to use it for themselves. see In re Gardner et al. 166 USPQ 138 (CCPA 1970).

Applicants' arguments filed 5/7/04 have been fully considered but they are not persuasive.

Applicants argue that specification page 7, lines 4-5 provide specific enabling support for claims 4-8 and 19-22.

It is the examiner's position that the specific portion of the specification where the applicants are referring to uses prophetic language to recite certain proposed concentrations of the composition.

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The claims recite a composition of about 0.03 wt% to about 0.3 wt% of IB-367. The specification is only enabled for a 0.3 wt% composition of IB-367 (see page 8 composition and page 11 experimental protocol). The instant specification invites the skilled artisan to experiment. Such is not seen as sufficient to support the breadth of the claims, wherein the scope of the claims encompasses a wider range of efficacy (i.e. lower ranges of about 0.03%) of the instantly claimed compounds and/or compositions.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

12. Claims 1-8 and 10-23 are rejected under 35 U.S.C. 103(a) as being obvious over Steinberg et al. I (WO 00/04915) and II (US 6,025,326). Prior art of record.

Claims are drawn to a method of preventing a respiratory infection (ventilator associated pneumonia) comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection.

Steinberg et al. (I) teach a method of preventing a respiratory infection comprising topically applying to the oral cavity of a patient a composition comprising an IB-367 peptide or a pharmaceutical acceptable salt thereof in an amount to prevent infection (see abstract, page 6, 9, 10, 23, 28, 36, figures 1-3 and claims specially claims 1, 20, 21, 23, 24, 25, 26 and 35-36).

Steinberg et al. (I) teach both native and hydrochloride salt of IB-367 (claims 20-21). Steinberg et al. (I) teach about 0.03 wt% to about 1 wt% of IB-367 (see claims 35-36). Steinberg et al. (II) teach topical oral formulations ranging from 0.001% (w/w) to 2.5 % active ingredient,

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different applications intervals such as 2, 3, 4 or even 6 times per day, treatment periods from 3-4 days or 1-4 weeks (see column 20, lines 15-55). Steinberg et al. do not specifically teach ventilator associated pneumonia. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the method and apply the composition taught by Steinberg et al. to the oral cavity of patients that is at-risk of developing VAP. It would have been expected, barring evidence to the contrary, that the composition taught by Steinberg et al. when administered would prevent VAP because Steinberg et al. (I) teach that their composition can be used in patients at high risk of developing pulmonary infections (i.e patients on ventilators) see abstract.

Conclusion

13. No claims are allowed.

14. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

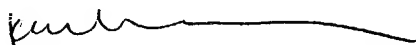
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnian-Shah whose telephone number is (571)-272-0863. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (571)-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

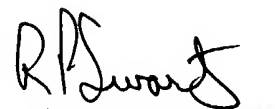


Khatol Shahnian-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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September 4, 2004



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER